



UNITED STATES PATENT AND TRADEMARK OFFICE

10
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/052,798 | 11/02/2001 | Camellia W. Adams | P1101R2D1 | 4012 |
| 9157 | 7590 | 06/27/2006 | EXAMINER | |
| GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080 | | | O'HARA, EILEEN B | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1646 | | |

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/052,798 | ADAMS ET AL. | |
| | Examiner Eileen B. O'Hara | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 April 2006.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 59-62 and 65-146 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 75-78 and 89-92 is/are allowed.
 6) Claim(s) 59-62,65-74,79-88 and 93-146 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 02 November 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Prosecution Reopened

1. The finality of the last office action is withdrawn due to a new grounds of rejection.

Claims Status

2. Claims 59-62 and 65-146 are pending in the instant application.

Withdrawn Rejections

3. The rejection of claims under obvious type double patenting is withdrawn in view of the abandonment of application 09/396,710.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 59-62 and 65-74, 79-88 and 93-146 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al., U.S. Published Application No. 20040136951, effective priority date March 17, 1997 (60/040,846). The effective filing date of the instant application is May 15, 1997.

Claims 59-62 and 65-146 encompass methods of inducing apoptosis in mammalian cancer cells comprising exposing the cells to an effective amount of agonistic antibody which

stimulates apoptosis, the antibody binds to Apo-2 polypeptide of amino acids 1-411 of SEQ ID NO: 1 or to extracellular domain of amino acids 1-182 or 54-182 of SEQ ID NO: 1, wherein the antibody may be monoclonal, single chain, chimeric, humanized, human, Fab fragment, scFv fragment, F(ab')2 fragment, wherein the cancer cells are breast, lung, colon or colorectal cancer cells, or glioma cancer cells, wherein the cancer cells are exposed to chemotherapy or radiation therapy, and wherein the antibody is fused to an epitope tag sequence.

Ni et al. disclose a protein disclosed as DR5 that is 99.6% identical to the protein of SEQ ID NO: 1 of the instant invention, having mismatchs at amino acids 32 and 410 (see attachment of alignment with parent 10/005842). Ni et al. also teach agonist antibodies to the protein. Since the proteins of the instant application and Ni et al. are almost identical, antibodies that bind to the protein of Ni et al. would also bind to the protein of SEQ ID NO: 1 of the instant application. Ni et al. also teach that the antibodies may be polyclonal or monoclonal (paragraphs 0212 and 0213) and may target the extracellular domain (paragraphs 0220, 0317, 0667), and that such agonist antibodies could be used to treat mammalian cancer cells including breast, lung, colon and glioma cancers (paragraphs 0023, 0319, 0342-0344, 0349-0350, 0371-0373 and 0375), and that the cancer cells may be exposed to chemotherapy or radiation therapy (paragraphs 0335-0336). Ni et al. also teach that the monoclonal antibodies may be single chain, chimeric, humanized, human, Fab fragment, scFv fragment, F(ab')2 fragment (paragraphs 0212 and 0213) and that the antibody may be fused to an epitope tag sequence (paragraph 0283). Therefore, Ni et al. anticipates the claims.

Conclusion

- 5.1 Claims 75-78 and 89-92 are allowed.
- 5.2 Claims 59-62 and 65-74, 79-88 and 93-146 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.
Patent Examiner

Eileen B. O'Hara
EILEEN B. O'HARA
PRIMARY EXAMINER